

REMARKS

Claims 3-6, 8-9, 11-12, 14-16, 19-22, 26-28, 30-32, 44, 48, and 55-88 were pending in this application at the time of the Office Action dated February 7, 2008.

By virtue of this response, claims 3-4, 6, 11-12, 20, 26-28, 30-32, 55-56, 58, 61-62, 64-65, 67, 70-71, 77, and 85 have been amended, and claims 8, 59, and 68 have been canceled. Claims 26-28 are amended to clarify that the solvent mixture comprises one or more hydrophobic solvents and one or more hydrophilic solvents, and that the one or more hydrophobic solvents have a solubility in water of less than 1 wt%. Claims 3-4, 11-12, 55-56, 61-62, 64-65, 70-71 are amended for consistency with claims 26-28. Claims 26-28 are amended to clarify that the amount of hydrophobic solvent(s) is at least 55%, and that this amount is specific to the hydrophobic solvent(s) within the mixture of the hydrophobic and hydrophilic solvents. Claims 26-28 are amended to include the limitation, "wherein the viscosity of the composition is less than or equal to 2000 centipoise." Claims 8, 59, and 68 are canceled as redundant in view of these amendments to claims 26, 27, and 28, respectively. Claims 30-32 are amended to clarify that the solvent system comprises a hydrophobic solvent and a hydrophilic solvent. Claims 6, 58, and 67 are amended to recite "wherein the beneficial agent in said composition has a concentration from 10 mg/ml to 100 ml/ml." Claims 20, 77, and 85 are amended to correct typographical errors. Support for the amended claims may be found in the specification and claims as originally filed, for example at, *inter alia*, paragraphs [0030] and [0041] of the application. No new matter is believed to be introduced by these amendments.

Accordingly, claims 3-6, 9, 11-12, 14-16, 19-22, 26-28, 30-32, 44, 48, 55-58, 60-67, and 69-88 are now pending and under examination.

With respect to all amendments and cancelled claims, Applicants have not dedicated or abandoned any unclaimed subject matter and, moreover, have not acquiesced to any rejections and/or objections made by the Office. Applicants expressly reserve the right to pursue prosecution of any presently excluded claim embodiments in future continuation, continuation-in-part, and/or divisional applications.

Information Disclosure Statements

Applicants respectfully request that the Examiner review and initial the Supplemental Information Disclosure Statements dated September 28, 2007 and October 31, 2007. Applicants also note that page 4 of the Information Disclosure Statement dated May 20, 2002 appears to be missing in the signed and initialed copy dated March 20, 2004. Applicants respectfully request that the Examiner review and initial page 4 of the Information Disclosure Statement dated May 20, 2002. A copy of the Information Disclosure Statement dated May 20, 2002 is enclosed herewith for the Examiner's convenience.

Claim Objections

Claims 4, 58, 65, 75, and 83 stand rejected under 37 CFR 1.75(c) as allegedly being of improper dependent form for failing to further limit the subject matter of a previous claim. The Applicants assume that the Examiner is referring to claim 56, and not claim 58.

Applicants respectfully submit that claims 4, 56, 65, 75, and 83 further limit the subject matter of previous claims 26, 27, 28, 31, and 32, respectively. Claims 26, 27, 28, 31, and 32 relate to compositions comprising one or more hydrophobic solvents having a solubility in water of less than 1 wt%, whereas claims 4, 56, 65, 75, and 83 relate to compositions comprising one or more hydrophobic solvents having a solubility in water of less than 0.1 wt%.

Accordingly, Applicants respectfully request withdrawal of the claim objections.

Claim Rejections – 35 USC § 112

(A) Claims 3-6, 8-9, 11-12, 14-16, 19-22, 26-28, 30-32, 44, 48, 55-58 stand rejected under 35 U.S.C. 112, first paragraph, for allegedly failing to comply with the written description requirement.

Regarding claims 26-28, the Examiner has asserted that the specification sets out that the amount of hydrophobic solvent is at least 55% at page 8, lines 14-18, and that this amount is specific to the hydrophobic agent within the mixture of the hydrophobic and hydrophilic solvents, and does not refer to the amount of both. Applicants have amended claims 26-28 to address the Examiner's rejection.

Regarding claims 6, 58, and 67, the Examiner has asserted that the original specification does not contain the range 10 mg/ml – 500 mg/ml. Applicants respectfully traverse this rejection and submit that this range is supported by the specification. Solely to advance prosecution and without acquiescing to the Examiner's rejection, Applicants have amended claims 6, 58, and 67 to recite "wherein the beneficial agent in said composition has a concentration from 10 mg/ml to 100 mg/ml."

Regarding claims 9, 60, and 69, the Examiner has asserted that the original specification sets out a range of "at least 25%" for the amount of beneficial agent released over 24 hours. Applicants respectfully traverse this rejection. The original specification, at *inter alia* original claim 9 and paragraph [0046], provide written description support for the limitation "wherein less than 25% of the beneficial agent in said composition is released in 24 hours following administration *in vivo*. For example, at paragraph [0046], the specification provides: "When the composition is administered *in vivo*, preferably less than 25% of the total amount of beneficial agent is released from the depot in 24 hours..."

Regarding claims 30-32, the Examiner has asserted that the claims should be rewritten so that it is clear that the solvent system, the beneficial agent, and the bioerodible polymer are separate components of the composition. Applicants have amended claims 30-32 to address the Examiner's rejection.

(B) Claims 26-28 stand rejected under 35 U.S.C. 112, first paragraph, as allegedly non-enabled for all viscosities.

Applicants respectfully traverse this rejection and submit that the claims are enabled in light of the teachings of the specification. Solely to advance prosecution and without acquiescing to the Examiner's rejection, Applicants have amended claims 26-28 to include the limitation, "wherein the viscosity of the composition is less than or equal to 2000 centipoise."

Accordingly, Applicants respectfully request withdrawal of the claim rejections.

CONCLUSION

In view of the above, each of the presently pending claims in this application is believed to be in immediate condition for allowance. Accordingly, the Examiner is respectfully requested to withdraw the outstanding rejection of the claims and to pass this application to issue. If it is determined that a telephone conference would expedite the prosecution of this application, the Examiner is invited to telephone the undersigned at the number given below.

In the event the U.S. Patent and Trademark office determines that an extension and/or other relief is required, applicant petitions for any required relief including extensions of time and authorizes the Commissioner to charge the cost of such petitions and/or other fees due in connection with the filing of this document to ***Deposit Account No. 03-1952*** referencing docket no. **146392000500**. However, the Commissioner is not authorized to charge the cost of the issue fee to the Deposit Account.

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Respectfully submitted,

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